§ 170.510 Types of certification.

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

§ 170.520 Application.

Applicants must include the following information in an application for ONC–ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to § 170.510. For authorization to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying, information including:

(1) Name, address, city, state, zip code, and Web site of applicant; and

(2) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(c) Documentation that confirms that the applicant has been accredited by the ONC–AA.

(d) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ACBs.

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

(a) Maintain its accreditation, or if a new ONC–AA is approved by the National Coordinator, obtain accreditation from the new ONC–AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation;

(b) Attend all mandatory ONC training and program update sessions;

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the ONC HIT Certification Program;

(f) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum:

(1) The Complete EHR or EHR Module developer name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been certified.

(8) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

(g) Retain all records related to the certification of Complete EHRs and/or EHR Module(s) for a minimum of 5 years;

(h) Only certify HIT, including Complete EHRs and/or EHR Module(s), that